

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

RAVGEN, INC.,

Plaintiff,

v.

NATERA, INC. and NSTX, INC.,

Defendants.

Civil Action No. 1:20-cv-00692-DAE

JURY TRIAL DEMANDED

**PLAINTIFF RAVGEN, INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR
LEAVE TO AMEND THEIR ANSWER AND DEFENSES**

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** As used herein, “Mot.” refers to Defendants’ Natera, Inc. and NSTX, Inc.’s Motion for Leave to Amend Their Answer and Defenses (Dkt. 287) **

I. INTRODUCTION

Natera cannot show the requisite good cause for its untimely amended answer. The entire factual basis for Natera’s proposed amendment is a June 2021 Patent License Agreement between Ravgen and third-party Thermo Fisher (“TF Agreement”) that was produced nearly two years ago on July 7, 2021, *during fact discovery* and prior to the 30(b)(6) deposition of Ravgen regarding patent licenses. During the *eleven months* between when Natera received the TF Agreement and when the Court stayed this case on May 31, 2022, Natera proceeded through fact discovery, expert discovery, dispositive motions, and pretrial disclosures without ever raising its new defense based on the TF Agreement. Tellingly, although two of Natera’s own experts analyzed the TF Agreement during expert discovery, no one ever asserted that the TF Agreement released or licensed Natera. In fact, Natera’s damages expert opined that the TF Agreement was “*not informative regarding a negotiation between Natera and Ravgen.*” See Ex. 1 ¶ 110.

Now that the stay is lifted and the parties are once again proceeding towards trial, Natera seeks to start from scratch and relitigate this case with a brand-new defense. The reason that Natera seeks a do-over is obvious. Since the parties prepared this case for trial in 2021, the defenses that Natera actually pursued have been rejected by district courts, a jury, and the Patent Office:

- **Infringement**: A jury in this District credited Ravgen’s infringement theory in awarding a verdict of willful infringement against *LabCorp*.¹ See Dkt. 257 at 10–11.
- **Damages**: The jury in *LabCorp* adopted the same damages theory Ravgen asserts in this case and awarded Ravgen \$272.5 million. *Id.*
- **Validity**: In response to Summary Judgement motions, the Court rejected Natera’s indefiniteness defense as well as its anticipation theories and issued a supplemental claim construction that substantially impacts Natera’s invalidity theories. See Dkt. 176. After a similar ruling on Summary Judgment in *LabCorp*, LabCorp withdrew all of its invalidity defenses midway through trial. *LabCorp*, Dkt. 199 at 1. Additionally, the Patent Office has repeatedly rejected prior art theories substantially similar to Natera’s. All *ten* IPR

¹ *Ravgen, Inc. v. Laboratory Corporation of America Holdings*, No. 20-cv-00969 (W.D. Tex.) (“*LabCorp*”).

proceedings against Ravgen's patents have concluded, and not a single claim has been invalidated. *See, e.g.*, Dkt. 274.

- **Enforceability:** The information that Natera alleges Ravgen withheld during prosecution is not material because it was all presented to the Patent Office in the ten separate IPRs, and the Patent Office upheld the validity of every claim.

With its best defenses rejected while this case was stayed, Natera seeks to begin this case anew to pursue the next-best defense it has now found: an alleged release and license based on the TF Agreement. But Natera's undue delay in raising that defense and the substantial prejudice to Ravgen precludes Natera from amending its answer to plead it now.

II. ARGUMENT

A. Natera Has Failed To Show Good Cause To Amend Under Rule 16(b).

Natera has failed to show that good cause exists to amend its pleadings under Rule 16(b) because: 1) Natera does not provide any explanation for its motion being filed *nearly two years* after the deadline to amend pleadings in this case; 2) the alleged importance is belied by Natera's remaining defenses and its experts' analysis of the TF Agreement; 3) Ravgen would be substantially prejudiced by having to re-do discovery to address new defense at this late stage and by continuing to extend this case; and 4) additional delay based on Natera's tactics would only further Ravgen's prejudice. *See Fahim v. Marriott Hotel Servs.*, 551 F.3d 344, 348 (5th Cir. 2008).

1. Natera Does Not And Cannot Explain The Extensive Delay Between Receiving The TF Agreement And Seeking Leave To Amend.

Natera cannot show good cause to amend because the only facts Natera pleads in its proposed amended answer were available when Ravgen produced the TF Agreement during fact discovery nearly two years ago, and it provides no explanation for its undue delay.

First, Natera asserts that "amending the Answer to assert the contract defense before the scheduling deadline was not possible." Mot. at 6. But even where new facts are uncovered after the deadline to amend, courts in this district routinely decline to find good cause where the moving

party provides no explanation for an additional delay between learning of the alleged new facts and moving to amend. *See, e.g., Miller v. Transp. Depot Produce & Dry, Inc.*, 2017 WL 11035598, at *3 (W.D. Tex. May 15, 2017) (finding undue delay where “even if the Court was to accept Defendant’s claim that they were not aware of facts for potential affirmative defenses” until after the deadline, defendant failed to adequately explain a four month delay between learning those facts and moving to amend); *Roque v. New 888 Rest., LLC*, 2015 U.S. Dist. LEXIS 129714, *26 (W.D. Tex. Sept. 28, 2015) (denying motion to amend because, while the movant did not learn of the proposed claims until after the deadline to amend, the movant failed to provide any explanation for waiting an additional two months to move); *ATD Combusters, LLC v. Ameritube, LLC*, 2019 U.S. Dist. LEXIS 149423, *11 (W.D. Tex. July 3, 2019).² Tellingly, Natera—which delayed two years (and *eleven months* before the stay)—does not cite any case where a court found good cause after a delay of more than even six months regardless of the explanation.

Natera’s new defense is based on the TF Agreement that was produced during fact discovery (before the 30(b)(6) deposition of Ravgen regarding patent licenses), was analyzed by multiple Natera experts, and was cited by Natera during dispositive motion briefing in *October 2021*. *See* Ex. 1 ¶ 110; Ex. 2 ¶ 33; Dkt. 104 at 3. Despite its availability and Natera’s reliance on the TF Agreement, Natera never asserted its new defense in any of its previous pleadings, contentions, or interrogatory responses during fact discovery or raise its claim during expert discovery or dispositive motion briefing. Natera offers *no explanation* for waiting almost two years—including eleven months before the case was stayed—after receiving the TF Agreement to attempt to amend its pleadings to add its new defense.

² Natera’s citation to *AT&T Corp. v. Park I-10 Motors*, 2014 WL 12690126, at *1-2 (W.D. Tex. Oct. 20, 2014) is inapposite because in that case the party moved to amend *less than a month* after discovering the new facts underlying the requested amendment.

Second, Natera asserts that the vacated *Quest* order³ and the December 2022 clarifying Amendment TF Agreement (Dkt. 282-1) (“TF Amendment”) were “significant developments,” (Mot. at 7), but these developments cannot explain Natera’s delay because ***Natera does not even mention them*** in its proposed amended answer, instead relying only on the TF Agreement.⁴ See Mot, Ex. A ¶ 109; see *Butler v. Taser Int’l, Inc.*, 535 F. App’x 371, 372 (5th Cir. 2013) (“to the extent [movant] obtained new facts in late depositions, those facts were not necessary to support” proposed new claims). Thus, Natera has been aware of the factual underpinnings of its new defense since Ravgen produced the TF Agreement during fact discovery in July 2021 and has not been diligent in pursuing the claim. See *Cole v. Sandel Med. Indus., LLC*, 413 Fed. App’x. 683, 689 (5th Cir. 2011). Accordingly, this factor strongly weighs against allowing the amendment.

2. Natera Maintains Several Additional Defenses And Counterclaims.

Natera’s proposed amendment is not important because Natera will still be left with the numerous defenses and counterclaims that it chose to pursue throughout fact and expert discovery.⁵ See, e.g., Dkt. 164 at 8–9; *Cantu v. Wayne Wilkens Trucking, LLC*, 2020 U.S. Dist. LEXIS 103104, *8–9 (W.D. Tex. June 11, 2020) (“[T]his is not a situation in which [movant] would be left with no remaining theory of recovery if [its] claim[] were not added, which weighs against finding that the proposed amendment is sufficiently important.”); *Joe Hand Promotions, Inc. v. Seay*, 2018 U.S. Dist. LEXIS 223774 at *9 (W.D. Tex. Sept. 26, 2018) (“[g]iven the untimeliness of the filing and [non-movant’s] ability to move forward under its original causes of action, the importance of

³ *Ravgen, Inc. v. Quest Diagnostics Incorporated*, No. 2:21-cv-09011-RGK-GJS (“*Quest*”), Dkt. 449 (C.D. Cal. Sept. 26, 2021) (“*Quest* order”).

⁴ The ***vacated Quest*** order is not a “‘fact’; it is a ruling by a trial court.” Cf. *Rural Water v. City of Guthrie*, 2014 WL 12836738, at *1 (W.D. Okla. Nov. 10, 2014).

⁵ Natera asserts that its new defense is “highly relevant to the proper resolution of this case.” Mot. at 7. But untimely motions to amend are routinely denied even if the proposed amendment may be case dispositive. See, e.g., *Fahim*, 551 F.3d at 348 (affirming denial of motion to amend where denial meant plaintiff could not recover damages).

the amendment is a thin factor”).⁶ Indeed, if Natera’s motion is denied, it would maintain potentially dispositive non-infringement theories, invalidity theories under 35 U.S.C. §§ 101, 102, 103, and 112, and unenforceability theories. *See* Dkt. 69 ¶¶ 104–106, 120–211; Dkt. 164 at 8–9 (Pretrial Order outlining Natera’s affirmative defenses and counterclaims litigated in this case).

Natera’s assertion that “Ravgen should not be permitted to seek hundreds of millions of dollars of damages on sales that it has already released and licensed” is not only contradicted by the plain language of the TF Agreement and the clarifying TF Amendment, but also by Natera’s own actions. Although Natera’s counsel and two of Natera’s own experts analyzed the TF Agreement in 2021, they never asserted that the agreement released or licensed any of Natera’s products. *See* Exs. 1, 2. In fact, Natera’s damages expert concluded that the TF Agreement was “*not informative regarding a negotiation between Natera and Ravgen.*” *See* Ex. 1 ¶ 110. That Natera never pursued this new defense despite having analyzed the TF Agreement, but instead pursued other defenses contradicts its assertion that this new defense is “important.” Accordingly, this factor weighs against allowing the amendment.

3. Natera’s Proposed Pleading Amendment Would Substantially Prejudice Ravgen.

Forcing Ravgen to address new claims this late in the case is substantially prejudicial to Ravgen because it could result in extensive discovery and extend the litigation. This warrants denial of Natera’s motion. *See Fahim*, 551 F.3d at 348 (finding granting the motion three months after the deadline had passed would prejudice the non-movant by forcing it to defend against a

⁶ Natera’s cited cases are distinguishable. First, *Crossroads Sys. v. Dot Hill Sys. Corp.*, 48 F. Supp. 3d 984 (W.D. Tex. Sep. 19, 2014) does not discuss Rule 16(b). Second, in *EMG Tech., LLC v. Vanguard Grp., Inc.*, 2014 WL 12597424 (E.D. Tex. Jan. 27, 2014) and *SimpleAir, Inc. v. AWS Convergence Techs.*, 2012 WL 12978325 (E.D. Tex. Jan. 31, 2012), both motions to amend came before discovery closed. Unlike in *EMG* and *SimpleAir*, any alleged relationship between Natera and Thermo Fisher has not been a “focal point throughout the pendency of this case,” highlighting Ravgen’s potential prejudice. *Id.* at *3; *EMG*, 2014 WL 12597424 at *3.

new claim late in the litigation); *Filgueira v. U.S. Bank Nat. Ass’n*, 734 F.3d 420, 423–24 (5th Cir. 2013) (finding prejudice dispositive because the untimely pleadings would cause the [non-movant] great expense and extend the litigation); *Sivertson v. Citibank, N.A.*, 2019 WL 12239629, at *3 (E.D. Tex. Apr. 22, 2019) (“[F]orc[ing] [non-movant] to now prepare for affirmative defenses that were not asserted previously . . . would be unfair and prejudicial”).⁷

First, Ravgen would be substantially prejudiced by being forced to address an entirely new defense this late in litigation that could require substantial new discovery. This case has been pending for almost three years and was five weeks from trial when the case was transferred from Judge Albright to Judge Yeakel “out of the blue” in November 2021. *See* Dkt. 257-2 at 6:18-19. Natera should not be allowed to prejudice Ravgen by imposing additional discovery on its new defense now. *See, e.g., Sivertson*, 2019 WL 12239629, at *3; *Beneplace, Inc. v. Pitney Bowes, Inc.*, 2016 U.S. Dist. LEXIS 196669, *28 (W.D. Tex. June 30, 2016) (“Regardless of the additional time potentially available to [non-movant] to conduct discovery, [non-movant] will be prejudiced by the need to engage in more discovery and investigation.”). Natera asserts that its proposed amendment “would not prejudice Ravgen because Ravgen already has the relevant facts and information.” Mot. at 7. Not so. The amount of additional document discovery, fact witness depositions, and expert discovery required by this new defense could be substantial, particularly because Natera’s proposed amendment fails to even identify any Thermo Fisher product used in Natera’s products that Natera alleges infringes Ravgen’s patents. *See* Mot., Ex. A ¶ 109 (alleging only that the accused products have “used Thermo Fisher equipment and consumables”); *see also S&W Enters. v. Southtrust Bank of Ala.*, 315 F.3d 533, 537 (5th Cir. 2003). Additionally, allowing

⁷ Natera’s citation to non-binding precedents where the motions to amend were filed *during fact discovery* do not mandate otherwise. *See* Mot. at 8. The parties here are “late in the litigation” and the potential prejudice to Ravgen is substantial. *Fahim*, 551 F.3d at 348.

Natera's proposed amendment would require burdening third party Thermo Fisher with additional document discovery and deposition testimony.

Second, Natera's belated proposed amendment will delay resolution of Ravgen's claims against Natera, further prejudicing Ravgen. *See Filgueira*, 734 F.3d at 423–24. Natera's prejudicial efforts to delay trial are evidenced by its proposed schedule in the parties' recent Joint Status Report. Dkt. 271. For example, while the parties previously *prepared the entire record through fact and expert discovery in just seven months* (see Dkt. 91-1 at 3–4), Natera now proposes *ten months* to "supplement" that record with six months of unbounded new fact discovery and four months of unbounded new expert discovery. Natera's unreasonable proposal would allow it to redo this case from scratch, needlessly harass third parties, unnecessarily waste immense Court and party resources, and unfairly delay resolution of Ravgen's claims. Accordingly, this factor strongly weighs against allowing the amendment.

4. A Continuance Would Only Further The Prejudice To Ravgen.

Natera's assertion that its proposed amendment "would not require a continuance" is based on Natera's unbounded and prejudicial proposal for supplemental discovery to address new facts that became available during the stay. *See* Dkt. 281 at 4–8. As Judge Yeakel recently told the parties, reopening discovery "does not mean . . . defendants get to allege different things." Ex. 3 at 11:24–12:6; *id.* at 24:12–15. Unlike in *LBS Innovations, LLC v. Aaron Bros., Inc.*, 2012 WL 12897919, at *2 (E.D. Tex. Nov. 9, 2012) cited by Natera, Natera's continued attempts to extend this case schedule are the exact prejudice to Ravgen. *Filgueira*, 734 F.3d at 424 (holding a continuance would not avoid the prejudice of additional expenses and extended litigation on the non-movant). Ravgen cannot retroactively pursue a new litigation strategy to address Natera's new, untimely defense without suffering prejudicial expense and time. *See Miller*, 2017 WL 11035598, at *4. Moreover, "as the party who created the delay in the first place," Natera should

not be entitled to a continuance. *Beneplace*, 2016 U.S. Dist. LEXIS 196669, *31–32. Accordingly, this factor strongly weighs against allowing the amendment. Because all of the factors weigh against allowing the amendment, Natera cannot show good cause, and its motion should be denied.

B. Natera’s Proposed Pleading Amendment Fails Under Rule 15(a).

Even if Natera could show good cause to amend under Rule 16(b) (it cannot), the Court should deny Natera’s proposed amendment under Rule 15(a) because: 1) Natera provides *no explanation* for its two-year delay in seeking to amend its pleadings before the stay; 2) Natera’s wait-and-see approach regarding its new defense indicates bad faith and dilatory motive; 3) Ravgen is prejudiced by being forced to address new claims with additional discovery this late in litigation; and 4) the amendment is futile. *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004).

First, Natera has not and cannot explain why it did not seek to amend its pleadings during the nearly eleven-month period after receiving the TF Agreement in fact discovery on July 7, 2021 to the Court’s Stay Order on May 31, 2022. *See Chitimacha Tribe v. Harry L. Laws Co.*, 690 F.2d 1157, 1163 (5th Cir. 1982) (“When there has been an apparent lack of diligence, the burden shifts to the movant to prove that the delay was due to excusable neglect.”); *Pharr v. Wille*, 2016 U.S. Dist. LEXIS 48937, *5 (W.D. Tex. Apr. 12, 2016) (“Although Rule 15(a) states leave to amend ‘shall be freely given when justice so requires,’ the district court may consider that the moving party failed to take advantage of earlier opportunities to amend.”). This unexplained delay of nearly eleven months can itself be fatal to Natera’s amendment. *See Smith*, 393 F.3d at 595 (“time delay on the part of a plaintiff can be procedurally fatal.”).

Second, Natera was aware of all of the facts allegedly supporting its proposed amendment during discovery and failed to plead them in an apparent attempt to gain a tactical advantage. *See Thomas v. Hughes*, 2018 WL 2996901, at *3 (W.D. Tex. Feb. 22, 2018) (“bad faith may bar amendment if the movant was aware of certain facts but failed to plead them in order to gain a

tactical advantage.”). Indeed, Natera’s proposed amendment ***does not plead a single fact that was unavailable during fact discovery in this case***. See Mot., Ex. A ¶ 109. However, instead of raising its new defense as this case progressed to trial, Natera chose to seek a stay and advanced multiple invalidity theories. Natera sought to add a new defense only after the Court made clear that the stay would be lifted and Natera would be left with invalidity challenges that Ravgen has successfully defeated in related proceedings. This type of “wait-and-see” approach to amending pleadings has been rejected by courts as indicating bad faith and dilatory motive. See *Wimm v. Jack Eckerd Corp.*, 3 F.3d 137, 141 (5th Cir. 1993); *Harmon v. Dallas Cnty., Texas*, 294 F. Supp. 3d 548, 568 (N.D. Tex. 2018) (“The Fifth Circuit has also admonished litigants for engaging in the type of “wait and see” approach . . . , particularly when a litigant is represented by counsel and fails to assert a claim as soon as he could have.”).

Third, as discussed above, allowing Natera to amend its pleadings would cause undue prejudice to Ravgen. See §II.A.3.; *Smith*, 393 F.3d at 596. Any prejudice to Natera by being “deprived of the opportunity to be heard on this defense” is of its own undue delay. Mot. at 9.

Finally, Natera’s amendment would be futile because it has not and cannot plead that ***both*** Ravgen ***and*** TF intended to benefit Defendants. See *MetCap Sec. LLC v. Pearl Senior Care, Inc.*, 2007 WL 1498989, at *7 (Del. Ch. May 16, 2007).⁸ Indeed, both the TF Agreement and the clarifying TF Amendment show the opposite. See Dkt. 281-4 at 2; Dkt. 282-1 at 1. The TF Agreement language [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] confirmed by the TF Amendment. Dkt. 282-1 at 1.

⁸ The TF Agreement is governed by Delaware law. See Dkt. 281-4 §8.13.

And, consistent with the intent of the TF Agreement, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] for patent infringement. *Id* at 2.

Natera has not pled, nor could it plead [REDACTED] infringe and/or that Natera's infringement would also [REDACTED]

[REDACTED] *Id*. Importantly, Natera's proposed amendment fails to identify any "Covered Product" used with Natera's products, let alone a "Covered Product" that Natera pleads is capable of infringing Ravgen's patents.

Natera's reliance on the *vacated Quest* order is misplaced.⁹ *See* Mot. at 10. The interpretation of the TF Agreement that was the basis for the order was an incorrect reading based on the clear language of the TF Agreement itself and further confirmed by the TF Amendment, which the *Quest* Court did not have. The *Quest* order was also vacated, so its incorrect interpretation did not face scrutiny on appeal and is not controlling in this or any other case. *See Quest*, Dkt. 492. Further, the *Quest* Court did not even address Delaware law requiring the parties to have intended to release third-party Natera, which Natera cannot plausibly plead. *MetCap*, 2007 WL 1498989, at *7. Natera's assertion that "the rights were irrevocably granted" is irrelevant. Mot. at 10. As the TF Amendment confirms, Natera is not an intended beneficiary and has no rights under the TF Agreement.

III. CONCLUSION

For the reasons above, Natera's motion should be denied.

⁹ Natera's reliance on the District of Delaware's recent order is similarly misplaced. *See* Mot. at 5. The defendants in those cases moved to amend their pleadings *before the deadline to amend pleadings*, before the *Markman* hearing, and early in discovery. *See Ravgen, Inc. v. Biora Therapeutics, Inc.*, No. 20-cv-01734-RGA-JLH, Dkt. 101 (D. Del. Mar. 28, 2023).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document and any attachments thereto via the Court's CM/ECF system and/or by electronic mail on April 21, 2023.

/s/ Kerri-Ann Limbeek (pro hac vice)

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